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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 24149-11 Eilaz Babaev 3047 10/06/2000 09/684,044 EXAMINER 7590 10/21/2003 THOMPSON, MICHAEL M George Likourezos Carter Deluca Farrell & Schmidt LLP PAPER NUMBER ART UNIT 445 Broad Hollow Road Suite 225 3763 Melville, NY 11747 DATE MAILED: 10/21/2003

18

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
		09/684,044	BABAEV, EILAZ	
	Office Action Summary	Examiner	Art Unit	
		Michael M. Thompson	3763	
Th MAILING DATE of this communication app ars on the cover sheet with the correspondenc address Period for Reply				
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status				
1)⊠	Responsive to communication(s) filed on 28 July 2003.			
2a)⊠	This action is FINAL. 2b) This	is action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.				
Disposition of Claims 4) M. Claim(a), 4.50 in/ore pending in the application				
•	Claim(s) <u>1-59</u> is/are pending in the application. 4a) Of the above claim(s) <u>2,3,5,7-13,15-24,26-31,33-39,43-49 and 53-58</u> is/are withdrawn from consideration.			
5)∐ 6\⊠	Claim(s) is/are allowed. Claim(s) <u>1,4,6,14,21,23,25,32,40-42,50-52 and 59</u> is/are rejected.			
	Claim(s) is/are objected to.			
8) Claim(s) are subject to restriction and/or election requirement.				
Application Papers				
9) The specification is objected to by the Examiner.				
10)⊠ The drawing(s) filed on <u>28 July 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.				
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).				
11)☐ The proposed drawing correction filed on is: a)☐ approved b)☐ disapproved by the Examiner.				
If approved, corrected drawings are required in reply to this Office action.				
12) The oath or declaration is objected to by the Examiner.				
Priority under 35 U.S.C. §§ 119 and 120				
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).				
a) ☐ All b) ☐ Some * c) ☐ None of:				
	1. Certified copies of the priority documents have been received.			
	2. Certified copies of the priority documents have been received in Application No			
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).				
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.				
Attachment(s)				
2) Notic	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Informal	y (PTO-413) Paper No(s) Patent Application (PTO-152)	
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DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 07/28/03 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered. It appears that the list or PTO-1449 has either been lost or has not been attached to the submission. Please submit an addition copy of the PTO-1449 for consideration.

Drawings

2. The drawings were received on 07/28/03. These drawings are acceptable.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 4. Claims 1, 4, 6, 14, 21, 23, 25, 50-52, and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Gutfeld et al. (5,013,241). Gutfeld et al. teaches a nozzle for ultrasound production of a sprayed liquid comprising a main body (collectively 14,18, 22) wherein the main body is close to the free distal end of the ultrasound transducer wherein the distal end of the body is coaxially placed and has a gap with the transducer tip. He teaches the main body being

Application/Control Number: 09/684,044 Page 3

Art Unit: 3763

connected to at least one reservoir (20 or 10) for delivering a solution wherein the reservoir may

be on top (20) or rigidly connected on the side (10).

Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- Gutfeld et al. ('241). Gutfeld et al. teaches all of the limitations of the claims except for explicitly designating the nozzle is made of one piece and whether or not the nozzle is sterile, sterilizable, or disposable. It would have been obvious to one having ordinary skill in the art, at the time the invention was made to make the nozzle as one piece, since it has been held that one-piece construction, in place of separate elements fastened together, is a design consideration within the skill of the art. In re Kohno, 391 F.2d 959, 157 USPQ 275 (CCPA 1968); In re

 Larson, 340 F.2d 965, 144 USPQ 347 (CCPA 1965). Furthermore, it is well known that dental tools are expected to be sterile and sterilizable while the disposability of an apparatus is delegated to the practitioner.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686

Art Unit: 3763

F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

8. Claims 1,4,6,14,21,23,25,32,40-42 and 50-52 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8 of U.S. Patent No. 5,076,266. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the patents claim similar subject matter to the instant application such as a nozzle for ultrasound production of a sprayed liquid comprising a main body wherein the main body is close to the free distal end of the ultrasound transducer wherein the distal end of the body is coaxially placed and has a gap with the transducer tip. The main body being connected to at least one reservoir for delivering a solution wherein the reservoir may be on top or connected on the side.

Terminal Disclaimer

9. The terminal disclaimer filed on 07/28/03 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of U.S. Patent No's 6,478,754 and 6,533,803 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Art Unit: 3763

Response to Arguments

10. Applicant's arguments filed 07/28/03 have been fully considered but they are not persuasive. It is the Examiner's position that previous rejection is still applicable with respect to the instant invention. The Examiner contends that von Gutfeld et al. teaches at least one reservoir connected to the main body for holding and delivering the treatment solution to the distal end or the marginally close radial side of the transducer tip via an opening substantially aligned with the free distal end of the ultrasound transducer tip. Furthermore, the definition of a spray is in fact a jet of liquid. The Examiner maintains that the liquid jet stream created by von Gutfeld et al. is in fact a spray if not by definition.

With respect to new claim 59 it is the Examiner's position that the prior art rejection extends to claim 59. Applicant's cited limitation pertaining to a housing dimensioned for housing at least a portion of the ultrasound transducer and for delivering the ultrasonic spray is in fact shown almost analogous to the main body of claims 1 and 50 the holder possibly being considered handle (30). In either event, claim 59 appears to only change the lexicography of the limitations.

In addressing Applicant's arguments with respect to the Double Patenting rejection of the Babaev '266 patent the Examiner respectfully disagrees with Applicant's arguments. The Babaev '266 patent is clearly teaching a device that is substantially similar to Applicant's device. The Examiner concedes that the limitations of Babaev '266 are far more limiting and specific as to structures within the device as claimed, however, the Examiner also considers Applicant's limitations to be *structurally* broader than the Babaev '266 patent. Although the instant claims elaborate more upon functional recitation, it is the Examiner's position that the functional

Art Unit: 3763

recitation provided in Applicant's claims are inherent to the claims 1-8 as recited in the Babaev

'266 patent. The scope of the claims as recited in Babaev '266 clearly includes similarly implied functionality. Statements made by Applicant on pages 18 and 19 appear to imply that the Babaev '266 patent does not provide, for instance, a fluid source (10) for introducing a fluid to a distal radiation surface (i.e. 26) via an opening (9, 12, 17) substantially aligned with the distal radiation surface. While portions of (12) and (9) may show alignment in terms of parallel alignment, portion (17) may show another alignment with the distal radiation surface. For these and similar reasons it appears that Applicant's arguments are not persuasive and the Double

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Patenting rejection of the Babaev '266 patent has been maintained.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Application/Control Number: 09/684,044

Art Unit: 3763

Page 7

Contacts

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Michael Thompson whose telephone number is (703) 305-1619. The Examiner can normally be reached on Monday through Friday from 9 am to 5 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Primary, Brian Casler, can be reached on (703) 308-3552. The official fax phone number for submissions to the organization where this application or proceeding is assigned is (703) 872-9302. The official fax phone number for submission of After Final response is (703) 872-9303.

Michael M. Thompson

Patent Examiner

BRIAN L. CASLER

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MT

October 18, 2003